

**NIH Blue Ribbon Panel to  
Advise on the Risk Assessment of the BU  
National Emerging Infectious Diseases Laboratories**

**Update on the Development of Principles and Best  
Practices for Community Engagement**

Advisory Committee to the Director, NIH  
June 4, 2009

**NIH Blue Ribbon Panel: Purpose**

- To provide scientific and technical advice to the NIH regarding the operation of a national biocontainment laboratory at Boston University Medical Center
  - Comments and concerns have been voiced by:
    - Courts
    - Local community
    - General public

**Two-Fold Charge to the Panel**

- BRP to advise on:
  - Studies to assess any potential public health risks associated with the operation of the National Emerging Infectious Diseases Laboratories and to assess strategies for mitigating these risks
  - Strategies to enhance local community engagement and communications regarding national and regional biocontainment laboratories

**Update on Supplementary Risk Assessment**

- Contract awarded in September 2008
- Broad range of infectious agents and scenarios
- Draft supplementary risk assessment released for formal public comment early 2010
- Process for development of supplementary risk assessment:
  - Ongoing oversight of study by the Blue Ribbon Panel
    - Open meetings with designated public comment period
  - NIH convenes the NRC for input into the development of the supplementary risk assessment to:

“...address whether the supplementary risk assessment is scientifically and technically sound in general and whether it addresses the public health concerns previously raised by the NRC in its review of the July 2007 DSRASSA.”

- Public comment always welcome

## **BRP Meetings with the Boston Communities**

- **May 16, 2008 (Boston)**
  - Presented the BRP charge and proposed approach to supplementary risk assessment
- **July 16, 2008 (Bethesda)**
  - Invited members of Boston community, Boston city officials, community researchers, and social justice experts
  - Explored case studies on community engagement and environmental justice
  - Roundtable discussion of how to effectively engage communities

## **BRP Meetings (cont'd.)**

- **October 14, 2008 (Boston)**
  - Engaged community members in planning of meeting and outreach efforts
  - Evening meeting in local community hall to:
    - Present and seek community input on draft principles and best practices for community engagement
    - Hear general comments and perspectives from community members

## **Principles and Best Practices for Public Engagement and Communication: Applicability**

- **Build on existing measures with the goal of achieving best practices**
- **Apply to Regional and National Biocontainment Laboratories funded by the NIH**
  - *NOTE: These concepts will be applicable to the Boston University NEIDL if the outcome of ongoing supplementary risk assessment studies and court cases leads to a decision to conduct research under high- or maximum-containment conditions.*
- **Are generally applicable to other high- and maximum-containment labs**

- Implementation of principles and practices will be left up to individual institutions

## **Recent BRP Activities**

- **December 2008 - Presentation of the draft principles and recommendations to the ACD**
- **Winter-Spring 2009**
  - Incorporation of the ACD's comments into the draft principles and recommendations
    - e.g., communication with local health care providers
  - Underscoring the importance of first-hand knowledge of biosafety procedures and practices
    - e.g., inclusion of lab technical staff on review committees
  - Further modifications to make the report more comprehensive and readable

## **Draft Principles**

- Rigorous, balanced, and transparent local biosafety review of proposed research
- Transparency regarding laboratory operations, research, and oversight
- Appropriate scientific and technical expertise
- Community engagement
- Engagement of local public health authorities
- Ongoing operations oversight

### **1. Rigorous, Balanced, and Transparent Local Biosafety Review**

- All high- and maximum-containment research at NIH funded RBLs and NBLs should undergo rigorous local biosafety review to ensure research will be conducted as safely and securely as possible
- Local review should:
  - Include appropriate breadth of scientific, medical, and technical expertise, drawing from outside the institution, as necessary
  - Provide for community representation

- Be “intellectually independent” so that reviewers are free of conflicts of interest
- Review should be on-going to ensure continued adherence to biosafety standards

## **2. Transparency Regarding Laboratory Operations, Research, and Oversight**

- To the extent possible, share with the public:
  - Details about the operation of the facility
  - Research agenda
  - Process for oversight of the facility and its associated research
- Examples of relevant details may include:
  - Risk (or perceived) risk of loss of containment of pathogenic organisms into the local or larger community
  - Results of risk-related evaluations done by oversight committees
  - Status of and changes in the oversight process

## **3. Appropriate Scientific and Technical Expertise**

- NIH-funded National and Regional Biocontainment Laboratories must have appropriately trained scientific and technical staff to ensure that the facility is operating as designed
  - Provide valuable oversight of biosafety practices
  - Ensure proper functioning of systems to maintain safe operations

## **4. Community Engagement**

- Institutions should foster communication with communities surrounding biocontainment facilities and provide:
  - Information about the about the planning, operation, and oversight of the facility
  - Mechanisms to convey concerns and ask questions
- Institutions should periodically revisit and evaluate, through a transparent and public process, the ongoing effectiveness of their community engagement activities
- **Engagement of Local Public Health Authorities**
- To promote public health and safety, institutions have a responsibility to:

- Apprise public health authorities of the agents under study at the facility
- Assist public health authorities, as appropriate, with the development of public health response plans
- Assist public health authorities, as appropriate, in addressing questions from local health care providers

## **6. Ongoing Operations Oversight**

- Rigorous oversight of the operation of biocontainment facilities is essential to ensure the safe and optimal operation of the facility as well as to foster and maintain public trust
- These activities will include:
  - Periodic review of protocols and all untoward events with potential public health implications
  - Select Agent inspections

### **Draft Best Practices**

- Transparent biosafety assessment of biocontainment research by an expert committee
- Communications about phase-in of high- and/or maximum-containment research operations
- Communications about the body of scientific and technical expertise applied to the operations of high- and maximum-containment laboratories
- Engagement of local public health authorities
- Ongoing community liaison activities

### **Draft Best Practices**

- Transparent biosafety assessment of biocontainment research by an expert committee
  - The BRP recommends that all high- and maximum-containment infectious disease research be reviewed, approved, and overseen by an institutional body (such as an IBC) that:
    - Has collective expertise in infectious disease research and biosafety principles and procedures
    - Includes at least one member representing the laboratory technical staff experienced in the implementation of biosafety practices
    - Is transparent by virtue of:
      - At least two non-institutional members to represent community interests

- Meeting minutes publicly available

## **Draft Best Practices**

2. **Communications about phase-in of high- and/or maximum-containment research operations**
  - **RBLs and NBLs should communicate specific information regarding safeguards and precautions utilized in phasing in research operations, for example:**
    - Testing of containment measures and verification of building systems
    - Conduct of low-containment research under maximum containment conditions for training
  - **Institutions should inform their communities and local public health authorities about plans for transitioning to a fully operational high- and maximum-containment laboratory**

## **Draft Best Practices**

3. **Communications about the body of scientific and technical expertise applied to the operations of high- and maximum-containment laboratories**
  - **Institutions should share information with the public about the range of expertise and activities undertaken that promote lab safety and secure biocontainment**
  - **As a special observation of the BRP, NIH should foster the professional development and continued training of biosafety and biocontainment professionals**

## **Draft Best Practices**

- **Engagement of local public health authorities**
  - **Public health authorities should be:**
    - Engaged early in the process of planning and construction
    - Informed of the research agenda and the types of organisms that will be used
    - Immediately notified of any untoward event that might have public health implications
  - **Communication should be established and maintained between the IBC and the public health authorities to include research underway and any pertinent safety issues that may arise**

## **Draft Best Practices**

- **Community liaison activities to promote openness and transparency about the lab's research agenda and biosafety record**
  - **These activities should be integrative and interactive and offer opportunities for:**
    - **Input from the community about impact of the lab**
    - **Communication to the community regarding lab operations**
    - **Education about the research programs and the public health benefits of the laboratory's research**

## **Request to Approve**

**The Blue Ribbon Panel presents these principles and best practices to the ACD for consideration and, as appropriate, approval.**

## **Discussion**